Ethylene Glycol Diacetate - Comments of Environmental Defense

(Submitted via Internet 9/4/02

(no company contact is listed on EPA's HPV web site))

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Ethylene Glycol Diacetate.

The test plan and robust summaries for ethylene glycol diacetate (EGD) were prepared by Eastman Chemical Company. EGD is used in thermoplastic acrylic coatings, as a reflow solvent and as an industrial intermediate in a number of applications. The sponsor concludes that existing data are adequate to fulfill the requirements of the HPV Program. While we do not necessarily disagree with this conclusion, key studies are omitted from the robust summaries making the test plan incomplete and non-reviewable at this time. The problem is that the sponsor relies almost entirely on data from a surrogate chemical to fulfill requirements for repeat dose, reproductive and developmental studies. However, neither experimental designs nor results for these studies are presented in the robust summaries or test plan. Instead, we are referred to assessments of these endpoints for the surrogate in the International Council of Chemical Associations (ICCA) initiative that is a companion to the HPV initiative. These data are not readily available, yet they are critical for evaluating data adequacy for EGD. Therefore, they need to be added to the robust summaries and test plan for EGD. This should be a straightforward and inexpensive undertaking, as the summaries must already have been prepared for the ICCA HPV documents. We would welcome an opportunity to review these summaries after they are incorporated into the EGD test plan.

The surrogate chemical used in this test plan is ethylene glycol (EG). The sponsor discusses, at length, the biologic plausibility that EGD should be rapidly metabolized to EG in most biological systems. No actual data on EGD metabolism is provided to support this discussion. We agree that such a metabolic pathway is likely as most cells in living systems contain esterases with high catalytic activity towards ester linkages. However, since this metabolic event is the cornerstone for the justification that data for EG can be used as a surrogate for EGD, we recommend that a simple metabolism study be conducted to confirm that EG is quantitatively liberated. This could be done quickly and inexpensively in isolated hepatocytes or another appropriate cell system and provide compelling evidence for using EG as a surrogate.

Thank you for this opportunity to comment.

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